

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>		Work Assignment Number 2-91								
		<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:								
Contract Number EP-C-14-001	Contract Period 11/01/2013 To 10/31/2016 Base                      Option Period Number 2	Title of Work Assignment/SF Site Name Notice of Proposed Rulemaking								
Contractor ICF INCORPORATED, L.L.C.		Specify Section and paragraph of Contract SOW D. Analysis, Documents and Issue Paper Preparation								
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 11/01/2015 To 10/31/2016								
Comments:										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:				LOE:				
11/01/2013 To 10/31/2016										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:		Cost/Fee				LOE:				
Cumulative Approved:		Cost/Fee				LOE:				
Work Assignment Manager Name    Waleska Nieves-Munoz						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number: 202-564-7103				
						FAX Number:				
Project Officer Name    Melissa Revely-Wilson						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number: 919-541-0207				
						FAX Number:				
Other Agency Official Name						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number:				
						FAX Number:				
Contracting Official Name    William Yates						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number: 513-487-2055				
						FAX Number:				

**PERFORMANCE WORK STATEMENT**  
**CONTRACT NO. EP-C-14-001**  
**WA 2-91**

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**TITLE:** Review, Analyze, Categorize Comments, and Provide Responses of Nondiscrimination Regulation Notice of Proposed Rulemaking

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**Specify Section & Paragraph SOW: D. Analysis, Documents and Issue Paper Preparation**

**PERIOD of PERFORMANCE:** Contract Award thru October 31, 2016

**I. BACKGROUND**

The EPA's External Compliance Program operates within the Office of Civil Rights (OCR) to ensure that recipients of EPA financial assistance and others comply with federal non-discrimination laws and EPA regulations implementing these statutes, found at 40 CFR Parts 5 & 7. Together, these statutes and implementing regulations prohibit discrimination on the basis of race, color, national origin (including limited-English proficiency), disability, sex, and age in programs or activities that receive EPA assistance.

The current nondiscrimination regulation Notice of Proposed Rulemaking (NPRM) is just one of several strategic measures being implemented to ensure prompt, effective, and efficient civil rights nondiscrimination complaint docket management and to enhance OCR's proactive compliance program. Since 2010, the EPA commissioned both an external review of its External Compliance Program by Deloitte Consulting, and an internal review by the EPA's Civil Rights Executive Committee. Accordingly, as part of its efforts to create a robust pre- and post- award compliance program (as identified in the EPA Draft EJ 2014 Plan Supplement), the EPA began the process of reevaluating its regulations to identify what data and information it currently obtains from recipients. This process resulted in the EPA benchmarking its regulations against those of other federal agencies and EPA's decision to bring its regulations into conformance with more than twenty other federal agencies. This NPRM is just one of several measures, which are more fully detailed in the Office of Civil Rights External Compliance and Complaints Program Draft Strategic Plan 2015-2020 (posted for comment on OCR's website on September 10, 2015 until March 12, 2016), to promote mission critical program and ensure prompt, effective and efficient complaint docket management.

In addition, EPA conducted several public meetings allowing discussion of the NPRM. The meetings were recorded by a stenographer and transcripts were submitted by the contractor. The public meetings were scheduled as follows:

1. Chicago, Illinois: January 11, 2016
2. Houston, Texas: January 12, 2016
3. Oakland, California: January 20, 2016
4. Research Triangle Park: January 15, 2016
5. Washington, DC: January 29, 2016
6. Washington, DC Howard University, March 3, 2016

## **II. PURPOSE**

The purpose of this work assignment is to review, organize, and categorize all comments received (in the public meetings and in the docket) regarding the NPRM, and construct potential responses. OCR will publish a Response-to-Comments document. There are a total of approximately 7,000 comments.

## **III. SCOPE OF WORK**

The contractor shall categorize, analyze, and present the comments received from the regulatory amendments in plain English and in user friendly format. Also, the contractor shall provide responses to the comments with recommendations and justifications. Analyzing and successfully completing this assignment requires previous knowledge of Title VI of the Civil Rights Act of 1964, EPA's regulations implementing Title VI and knowledge of OCR's *2000 Draft Revised Investigations Guidance*, *OCR's External Compliance Strategic Plan for 2015-2020*, OCR's Role of Complainants, and Recipients in the Title VI investigation process and OCR's *2015 Interim Case Resolution Manual*.

### **TASK 1: Establish Communication**

Within three (3) days of the start date of this work assignment (WA), the Contractor and any appropriate contractor staff shall schedule a conference call (not to exceed 1 hour) with the work assignment manager (WAM) and other EPA staff to clarify outstanding questions and to confirm the schedule of specific tasks. Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the Project Officer.

### **TASK 2: Work Plan and Staffing Plan**

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan. This Staffing Plan should list personnel assigned by task, and the qualifications of the proposed personnel.

### **TASK 3: Inventory & Review of Comments**

The contractor shall support EPA by:

- a. Creating an inventory of comments (tracking spreadsheet)
  - Identifying any duplicates (multiple versions from same commenter)
  - Categorizing commenters by affiliation, e.g.
    - Congress
    - Tribe
    - Private citizen
    - State government and government associations
    - County/local government and associations
    - Academia
    - Non-governmental organization (nonprofit)
    - Industry/industry trade association/chamber of commerce
    - Anonymous
    - Other
- b. Categorizing commenters by themes and subcategories as follows:
  - Procedures
    - Selective/Discretionary Investigation (Practices)

- General Criticism
  - General Suggestions and Recommendations
  - Accountability
  - Stakeholder Involvement and Outreach
  - Timelines/Deadlines
  - Policies
    - Influences/Program Objectives
    - Accountability
    - Suggested Regulation Revisions and Additions (Language/Substantive)
    - Historical Comment on Past Practices
    - General Criticism
    - General Suggestions/Recommendations
  - Resources/Needs/Improvements
    - OCR Performance
    - Transparency
  - T6 Complaints and Concerns
    - State Level Regulatory Agency Concerns
  - Environmental Justice Issues
- c. Identifying:
- Duplicate/Identical Submissions
  - All Comments Regarding the Interim Case Resolution Manual
  - All Comments Regarding the Strategic Plan
- d. Preparing a draft report and a draft summary report of comments including:
- Listings and counts of commenters by affiliation
  - Listings and counts of comments by topic/issue
  - Summaries of frequently raised, detailed, and unique comments/issues
  - A review and assessment of comments discussing consistent or consensus messages, comparison of conflicting perspectives, and potential conflicts
- e. Submitting final documents (see the deliverable section)

In the event that there is a need to provide further clarification, a technical directive document (TDD) will be submitted. All material developed should be reviewed and approved by the WAM or Alternate WAM. Draft documents should be provided on Microsoft Word. Final product specifications will be outlined in TDDs.

#### **TASK 4: Draft Potential Responses to Comments**

Based on the results of the comments analysis, the contractor shall support EPA by:

- Preparing a draft report of options and recommendations/suggestions, with justifications based on the comments, for the regulatory amendments for OCR to consider
- Developing a draft outline of the comment summary report and the recommendations report
- Preparing a draft and final summary response to comment document
- Creating an inventory of comments and responses (tracking spreadsheet)
- Submitting final documents ( see the deliverable section)

In the event that there is a need to provide further clarification, a technical directive document (TDD) will be submitted. All material developed should be reviewed and approved by the WAM or Alternate WAM. Draft documents should be provided on Microsoft Word. Final product specifications will be outlined in TDDs.



## **TASK 5: Ad Hoc Support**

The contractor shall provide support to EPA on an ad hoc basis. The details of the support required will be outlined in the TDD, in which other tasks described in this WA may overlap. In general, ad hoc support will include research, collection, analysis, and technical review of documents in order to review and categorize the comments received to support this initiative and EPA in general. In addition, under this task EPA anticipates issuing up to two (2) ad hoc requests in this contract. For estimation purposes, ad hoc requests may average 15 hours each and may require up to two (2) pages of narrative report.

## **IV. TIME SCHEDULE AND DELIVERABLES**

The deliverables shall be due as stated below. The contractor shall provide the WAM with one (1) copy of all deliverables and drafts. Electronic files shall be provided in lieu of hard copy where appropriate (i.e., html files to be posted on the web, etc.) Electronic files must also be provided upon completion of the work assignment.

### **List of Deliverables**

Deliverable	Due Date
<b>Task 1 : WORD ASSIGNMENT MANAGEMENT</b>	
Task 1. Initial Conference Call	3 days after award of Work Assignment
<b>TASK 2: WORK PLAN AND STAFFING PLAN</b>	
Task 2. QAPP	20 days after award
<b>TASK 3 INVENTORY AND REVIEW OF COMMENTS</b>	
<ul style="list-style-type: none"><li>• Deliverable</li></ul>	EPA WAM will clarify in work plan kickoff meeting and subsequent TDDs as needed, however, the draft inventory and review of comments will be completed by no later than 15 days of the date of the award of this contract.
<b>TASK 4 DRAFT POTENTIAL RESPONSES TO COMMENTS</b>	
Deliverable	EPA WAM will clarify in work plan kickoff meeting and subsequent TDDs as needed, however, draft potential responses to comments should be completed by no later than 30 days of the date of the award of this contract.
<b>Task 5: Ad Hoc SUPPORT</b>	

Deliverable	Due Date
Deliverable	Up to (two) 2 Contract Award thru October 31, 2016; EPA WAM will clarify in TDD
Meeting attendance	
	Up to five (5) Contract Award thru October 31, 2016; EPA WAM will clarify in TDD

## **V. MANAGEMENT CONTROLS**

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

## **VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT**

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the project officer (PO), WAM, or contracting officer (CO).

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA.

## **VII. SPECIAL CONDITIONS AND ASSUMPTIONS**

The contractor shall hold a conference call with the WAM at the initiation of the work assignment. Standard reporting requirements of the contract apply for active/completed projects.

## **IX. OTHER REQUIREMENTS**

The WAM will have oversight on all materials developed by the contractor. The primary communication mechanism between the WAM and the contractor shall be email.

In cases where the work to be performed is of a highly scientific or technical nature or requires consultation or interactions, it may be more expedient for the contractor to interact directly with members of the scientific/technical staff.

## **IX. QUALITY ASSURANCE (QA) REQUIREMENTS**

Check [ ] Yes or [x ] NO, if the following statement is true or false. The Contractor shall submit a written Quality Assurance Project Plan for any project that is developing environmental measurements or a Quality Assurance Supplement to the Quality Management Plan for any project which generates environmental data using models with their technical proposal.

Work Assignment CORs will provide additional information here, if Yes is checked above

## **X. EPA CONTACT INFORMATION**

Copies of all correspondence pertaining to the performance of this WA shall be sent to the PO.

**WORK ASSIGNMENT MANAGER:** Waleska Nieves-Muñoz  
1200 Pennsylvania Avenue, NW  
Washington, D.C. 20460 MC: 1201A  
202-564-7103  
[nieves-munoz.waleska@epa.gov](mailto:nieves-munoz.waleska@epa.gov)

**ALTERNATE WORK ASSIGNMENT MANAGER:** Emilio Cortes  
1200 Pennsylvania Avenue, NW  
Washington, D.C. 20460 MC:1201A  
202-564-  
[Cortes.emilio@epa.gov](mailto:Cortes.emilio@epa.gov)

**EPA**United States Environmental Protection Agency  
Washington, DC 20460**Work Assignment**Work Assignment Number  
2-92☐ Other ☐ Amendment Number:Contract Number  
EP-C-14-001Contract Period 11/01/2013 To 10/31/2016  
Base Option Period Number 2Title of Work Assignment/SF Site Name  
Toxicological support for IRISContractor  
ICF INCORPORATED, L.L.C.Specify Section and paragraph of Contract SOW  
Section A task1Purpose: ☒ Work Assignment  
☐ Work Assignment Amendment  
☐ Work Plan Approval☐ Work Assignment Close-Out  
☐ Incremental Funding

Period of Performance

From 06/15/2016 To 10/31/2016

Comments:

☐ Superfund

## Accounting and Appropriations Data

☒ Non-SuperfundSFO  
(Max 2)☐

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

## Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2016 Cost/Fee: LOE:

This Action:

Total:

## Work Plan / Cost Estimate Approvals

Contractor WP Dated: Cost/Fee: LOE:

Cumulative Approved: Cost/Fee: LOE:

Work Assignment Manager Name Jenny Li

(Signature) (Date)

Branch/Mail Code:

Phone Number: 703-347-8577

FAX Number:

Project Officer Name Melissa Revely-Wilson

(Signature) (Date)

Branch/Mail Code:

Phone Number: 919-541-0207

FAX Number:

Other Agency Official Name

(Signature) (Date)

Branch/Mail Code:

Phone Number:

FAX Number:

Contracting Official Name William Yates

(Signature) (Date)

Branch/Mail Code:

Phone Number: 513-487-2055

FAX Number:

**PERFORMANCE WORK STATEMENT**  
**CONTRACT NO. EP-C-14-001**  
**WA 2-92**

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**TITLE:** Toxicological Support for IRIS Program's Disciplinary Workgroups

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**PERIOD OF PERFORMANCE:** CO Approval – October 31, 2016

## **I. PURPOSE**

The purpose of this work assignment is to provide services to disciplinary workgroups in the U.S. Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) Program. The specific purpose is to provide expert toxicological support for the development of Integrated Risk Information System (IRIS) scientific materials, including development of protocols to systematically assess experimental methods used to examine toxicity endpoints, analysis of study quality consistent with systemic review approaches, tabular and graphical display of toxicity data, and syntheses of animal toxicity data.

## **II. BACKGROUND**

EPA's Integrated Risk Information System (IRIS) is a human health assessment program that evaluates qualitative and quantitative risk information on health effects that may result from exposure to environmental contaminants. When supported by available data, IRIS provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic noncancer health effects, and oral slope factors and inhalation unit risks for carcinogenic effects. IRIS contains chemical-specific summaries of qualitative and quantitative health information in support of two steps of the risk assessment process, i.e., hazard identification and dose-response evaluation. By combining IRIS toxicity values with specific exposure information, government and other entities use IRIS to help characterize public health risks of chemicals and thereby support risk management decisions designed to protect public health.

The development of IRIS assessments is accomplished by chemical assessment teams and disciplinary workgroups. The disciplinary workgroups include scientists with expertise in specific scientific disciplines. These workgroups develop scientific approaches to implementation of systemic review methods, and develop and review hazard sections for specific IRIS chemical assessments. Chemicals on the IRIS multiyear agenda, and that may be the subject of tasks under this work assignment (WA), can be found at <https://www.epa.gov/iris/iris-agenda>.

## **III. SCOPE OF WORK: TASKS AND DELIVERABLES**

### **Requirements Specific to this Work Assignment**

Under this WA, an episode of work (aka "request") will be initiated by written Technical Direction (TD). Each request will clarify deadlines for delivering drafts and final work products.

An initiating TD will identify the data and the specific tasks (as outlined below) to be performed.

The Contractor shall prepare documents under the guidance of *IRIS Handbook of Operating Procedures for Systematic Review of Environmental Health Hazards* (aka the “Handbook”, to be provided by EPA) and in the format specified in the TD. Recent examples of final and draft assessments for other chemicals or scientific materials such as evidence tables and exposure-response arrays, may also serve as models. Documents shall be technically edited for format and grammar before being delivered to the EPA Work Assignment Manager (WAM).

The Contractor will be given an account in HERO (Health and Environmental Research Online), with access to scientific literature. Copyright law of the U.S. (Title 17 U.S. Code) governs the making of reproductions of copyrighted material. Section 107 of the copyright act instructs that, “the fair use of a copyrighted work for purposes such as ... research, is not an infringement of copyright.” The Contractor is liable for any infringement of copyright. To set up the HERO account, the Contractor shall send an email to [hero@epa.gov](mailto:hero@epa.gov) - and include the following information: Names, addresses, phone numbers, emails of all contractors needing HERO accounts, project name, start date and end date. The contractors will receive their HERO account information, with user documentation, within 3 business days.

HERO shall be used for performing literature searches. The literature search shall include, at a minimum, the following databases: PubMed, Web of Science, ToxNet; but may include others, as appropriate. The results from the literature search shall be submitted to HERO, as described in the user documentation. EPA will provide the PDFs through the HERO interface.

The Contractor shall use HERO (Health and Environmental Research Online) for reference citation and bibliographic generation, as described in the user documentation.

The Contractor will develop and maintain internal documentation and data pertaining to all assumptions, data sources, databases, procedures, statistical analyses, and computer programming code, scripts, and software instructions used to support and execute EPA's requirements and deliverables, in order that results can be replicated. The contractor will provide access to this internal documentation upon request by the EPA WAM or EPA Project Officer.

### **Task 1: Develop a Work Plan**

The Contractor shall prepare a written work plan proposing a technical approach to the work assignment. The work plan shall outline how the work shall be performed and provide a list of deliverables and interim deliverables with the schedule for completion. In addition, the budget and staffing plan and a brief description of the qualifications of the key technical staff shall be included. The Contractor shall maintain communication with the WAM through weekly phone calls or email updates.

Deliverable Schedule: Work plan due in accordance with the contract.

## **Task 2: Quality Assurance Project Plan (QAPP)**

The Contractor shall develop a QAPP for this WA. The Contractor must address in the QAPP how environmental or health data from existing sources, such as published studies, will be considered for the WA, since these data were developed for a different purpose. This includes data used from citations found in the literature. Specifications for QAPPs prepared for activities funded by the EPA are available at <http://www.epa.gov/QUALITY/qadocs.html>. The QAPP is to be compliant with R-5 requirements. Guidelines for developing quality documents for non-EPA organizations are available at <http://www.epa.gov/QUALITY/exmural.html>.

Deliverable Schedule: QAPP due in accordance with the contract.

## **Task 3. Kick-off Conference Call**

The Contractor shall schedule a conference call with the EPA WAM to discuss all tasks and to clarify any specific issues. The Contractor will distribute meeting minutes of the topics discussed and any action items agreed to within 3 days after the conference call.

Deliverable Schedule: Within 2 days after receipt of approved assignment.

## **Task 4: Manage, Identify and Recruit Expert Toxicologists**

The Contractor shall identify, recruit and manage expert toxicologists (“experts”) to develop scientific materials as specified by technical direction. The Contractor shall be responsible for ensuring timely communication is passed between the EPA WAM and the experts so that technical clarification can be offered and interaction between EPA and the experts can occur as needed. The Contractor shall also ensure that the deliverables are provided to the EPA WAM in a timely manner.

EPA may seek to identify and recruit experts to support the following subtasks (discussed further in Task 5 within this WA):

- 1) Development of protocols that systemically assess study methods examining toxicity endpoints;
- 2) Evaluation of quality of animal toxicological studies;
- 3) Evidence tables of specific health effects;
- 4) Graphical displays of evidence of specific health effects;
- 5) Other toxicological support (data synthesis, expert opinion, white papers, etc.).

EPA will provide guidance for the development of evidence tables and templates of the evidence and summary tables. The chemical assessments and related documents that will require assistance under this WA will be clarified through technical direction.

The EPA assumes primary authorship in the writing process for all materials and contributing experts are listed in the final documents as appropriate. EPA will approve each of the experts performing work within two days of notification of a potential candidate.

## **Subtasks**

### **1) Identify and Recruit Expert Toxicologists**

The Contractor shall identify and contact experts with a knowledge base that is aligned with the descriptions in each written TD. Each TD will specify the minimum/desired qualifications of the experts for that chemical assessment. The expertise needed will be specific to the broad field of toxicology. Potential experts shall be asked to submit a bio-sketch to ensure they meet the minimum/desired qualifications, and EPA will notify the Contractor of its concurrence with the selection.

### **2) Manage Expert Toxicologists**

The Contractor shall manage the recruited experts and ensure timely communication occurs between EPA and the experts. This shall involve setting up conference calls with the experts and EPA staff. In addition, the Contractor shall ensure that the written sections, comments and draft reviews are progressing on schedule and are delivered by the deadlines noted in this WA.

Deliverable Schedule: The schedule and specific expertise requested will be clarified within a TD.

## **Task 5. Complete Subtasks as Directed by EPA**

The specific subtasks under this performance work statement (PWS) are described below. Subtask 1 addresses systematic review methods in general and is not specific to any chemical. Subtasks 2 to 5 are chemical specific. Specific clarification will be provided by the EPA WAM through Technical Direction. Technical Direction will be submitted individually for each project, and the subtasks to be completed will be project-specific (i.e., not all of the subtasks will be completed for each project). The focus of work during this option period is on Subtask 1, Development of Evaluation Protocols. For purposes of cost proposal estimation, the Contractor should assume that up to three work products will be performed under this WA, and that two of these work products will be performed by TD under Subtask 1. The Contractor should assume that the third work product would be conducted under one of the remaining subtasks (i.e., Subtask 2 to 5), would involve a moderate level of effort (e.g., less than 100 hours of staff time), and not require expert consultation.

1) Development of evaluation protocols. The protocols are a set of criteria used to systemically assess study methods. By assessing a series of specific features, potential methodological considerations that could affect the interpretation of or confidence in the toxicity endpoint results is evaluated. For each endpoint within a broader health outcome, the following five features are assessed: test animal allocation, exposure design, experimental variables, endpoint measurements, results presentation. Besides evaluation of these five features, the protocol document shall include an introductory background section, an overall summary section, and



criteria to use for characterizing study methods as “highly informative,” “informative,” “less informative,” and “uninformative.”

The Contractor shall identify and recruit toxicologists with demonstrated expertise in the endpoints for which a protocol is to be developed, based in part on publication record. For each endpoint under discussion (e.g., thyroid hormones), two experts will typically be needed. The Contractor shall send EPA the resumes of potential experts so that a determination can be made that the individuals have the required expertise. For each toxicity endpoint, EPA will provide preliminary protocol materials and a set of toxicology papers for purposes of discussion, and will collaborate with the experts to develop the protocol. The Contractor shall facilitate drafting and revising the protocol by arranging periodic discussions between the experts and EPA scientists. Protocol development for toxicity endpoints will parallel the efforts on the development of outcome protocols for epidemiology endpoints that ICF is currently supporting.

2) Evaluation of quality of animal toxicological studies. The Contractor shall abstract relevant details (experimental design, exposure, endpoint evaluation and analysis and presentation of results) of individual studies to allow for evaluation consistent with the systematic review process. The purpose of this task is to evaluate studies with respect to reliability and utility of the study, and documenting study evaluation in tables. As necessary, the Contractor shall provide and manage experts to perform this task.

Study quality evaluations should be independent of considerations regarding the direction or magnitude of study results. Study quality evaluations will be performed at an early stage of assessment development, i.e., after identifying the relevant sources of primary data but before developing evidence tables and characterizing hazard associated with chemical exposure. EPA will provide templates or databases for the Contractor to use in abstracting study information. The specific details as to what should be abstracted will be determined through consultation with the EPA WAM.

3) Evidence tables. The Contractor shall prepare evidence tables that summarize results from toxicological studies, consistent with the Handbook. The Contractor shall also conduct quality assurance (QA) checks of evidence tables developed by experts and/or provided by EPA. As necessary, the Contractor shall provide and manage experts to perform this task.

4) Graphical displays. The Contractor shall prepare graphical displays of results from toxicological studies. The types or formats of the graphical presentation of the toxicological results shall be discussed between EPA and the Contractor. The Contractor will provide expertise to develop or modify graphical displays as needed. The Contractor shall also conduct quality assurance (QA) checks of the data used to generate graphical displays. As necessary, the Contractor shall provide and manage experts to perform this task.

5) Other toxicological support. The Contractor shall address other issues that may arise within the context of the review of toxicological studies. These issues may pertain to interpretation of specific results in toxicological studies, synthesis and dose-response analysis of toxicological data. As necessary, the Contractor shall provide and manage experts to perform this task.

Deliverable Schedule: The deliverable schedule will vary depending on the subtask(s) and chemical, and will depend on the amount and complexity of the information to be evaluated/summarized. The schedule will be clarified within a TD.

#### **Task 6. Revision of Task 5 Deliverables**

EPA will submit comments on the task 5 deliverables. The Contractor shall provide and manage expert toxicological expertise to revise those deliverables based on EPA comments. The use of “redline” versions (track changes) of the document will be employed throughout the process. Tasks issued under this WA will be completed when all EPA comments have been considered and addressed, and may require multiple rounds of revision.

Deliverable Schedule: The deliverable schedule will vary depending on the subtask(s) and chemical. Unless otherwise specified in the TD, the Contractor will incorporate EPA comments within 7 days of receipt. The schedule will be clarified within the TD.

### **V. SCHEDULE OF DELIVERABLES**

This schedule and the deliverables dates specified under each Task above may be further clarified using written Technical Direction.

<b>Task</b>	<b>Schedule</b>
1. Develop a Work Plan	In accordance with contract
2. Quality Assurance Project Plan	In accordance with contract
3. Kick-off Conference Call	Within 2 days after the approval of the assignment
4. Manage, Identify and Recruit Expert Toxicologists	To be clarified in written technical direction.
5. Complete Subtasks as Directed by EPA	To be clarified in written technical direction.
6. Revision of Task 5 Deliverables	To be clarified in written technical direction.

### **VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT**

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA. The Contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

## **VII. SPECIAL CONDITIONS AND ASSUMPTIONS**

The contractor shall provide regular updates on progress and any issues that need to be resolved to the WAM by telephone or by email. Any technical directions made during informal discussions shall be issued promptly by the EPA WAM in writing (to include email).

## **VIII. EPA CONTACTS**

### EPA Work Assignment Manager (WAM)

Jenny Li, PhD, DABT

703-347-8577

li.jenny@epa.gov

#### Mailing Address:

1200 Pennsylvania Ave. NW

U.S. EPA, ORD/NCEA (MC8601-P)

Washington DC, 20460

#### Courier Deliveries:

U.S. EPA, Office of Research and Development, National Center for Environmental Assessment

11<sup>th</sup> floor, Cubicle # 11227

2733 Crystal Dr., Arlington, VA 22202

### EPA Alternate Work Assignment Manager (Alt-WAM)

Marian Rutigliano, DO, MSEV

703-347-0186

Rutigliano.marian@epa.gov

#### Mailing Address:

1200 Pennsylvania Ave. NW

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#### Courier Deliveries:

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2733 Crystal Dr., Arlington, VA 22202

**EPA**United States Environmental Protection Agency  
Washington, DC 20460**Work Assignment**Work Assignment Number  
2-93☐ Other ☐ Amendment Number:Contract Number  
EP-C-14-001

Contract Period 11/01/2013 To 10/31/2016

Title of Work Assignment/SF Site Name

Base Option Period Number 2

Workshop

Contractor  
ICF INCORPORATED, L.L.C.Specify Section and paragraph of Contract SOW  
A. Assessment Issues and Documents,Purpose:  
☒ Work Assignment  
☐ Work Assignment Amendment  
☐ Work Plan Approval☐ Work Assignment Close-Out  
☐ Incremental Funding

Period of Performance

From 11/01/2015 To 10/31/2016

Comments:

☐ Superfund

## Accounting and Appropriations Data

☒ Non-SuperfundSFO  
(Max 2)☐

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

## Authorized Work Assignment Ceiling

Contract Period:  
11/01/2013 To 10/31/2016

Cost/Fee:

LOE:

This Action:

Total:

## Work Plan / Cost Estimate Approvals

Contractor WP Dated:

Cost/Fee

LOE:

Cumulative Approved:

Cost/Fee

LOE:

Work Assignment Manager Name Melissa Mccullough

Branch/Mail Code:

Phone Number: 919-541-5646

FAX Number:

(Signature)

(Date)

Project Officer Name Melissa Revely-Wilson

Branch/Mail Code:

Phone Number: 919-541-0207

FAX Number:

(Signature)

(Date)

Other Agency Official Name

Branch/Mail Code:

Phone Number:

FAX Number:

(Signature)

(Date)

Contracting Official Name William Yates

Branch/Mail Code:

Phone Number: 513-487-2055

FAX Number:

(Signature)

(Date)

**PERFORMANCE WORK STATEMENT**  
**Contract No. EP-C-14-001**  
**WA 2-93**

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**Title: Support for ISSCO Development Stakeholder Workshop**

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**Specify Section & Paragraph SOW:** A. Assessment Issues and Documents, 4. Public Health Outcomes and E. Risk Assessment Support - Meetings

**PERIOD of PERFORMANCE: CO Award – September 30, 2016**

**I. PURPOSE:**

The purpose of this Work Assignment is to provide administrative and logistical/facilitation support services for one face-to-face Stakeholder Workshop, to be held in Research Triangle Park, NC, adjacent to the cross-ORD Project Leads meeting in August, 2016. This work assignment is consistent with the purpose and scope of Contract EP-C-09-009.

**II. BACKGROUND:**

The Sustainable and Healthy Communities (SHC) was created to provide information and tools to inform decisions that affect local sustainability, to better foster long term environmental, economic and social good. From the beginning of the program, stakeholder and partner input has guided what and how SHC outputs can best serve those needs. However, continuing advances in community sustainability practice and available tools/data can potentially make planned SHC research off target, as well as provide updated material for or complementing research products. To address these issues, SHC attempts to remain informed about stakeholder needs as they evolve. While SHC research is sketched out for through 2019, details are being solidified for projects farther out, and project management guidelines recommend periodic evaluation to adjust projects where needed to hit targets. At this point, SHC has mapped the program's projects as they are designed to fulfill programmatic objectives, and the program has determined that outreach to the user audience will be critical to focusing the final outputs toward what will make them most useful.

**III. STATEMENT OF WORK:**

**A. Objective:**

The overall objective of this work assignment (WA) is to provide administrative and logistical support for one meeting of community sustainability stakeholders that support community decision making toward

Sustainability. Support can include planning for meeting and logistics, travel support, onsite meeting support and facilitation, a summary report (including meeting and breakout discussion notes), communication activities related to the meeting and coordinating an evaluation mechanism to solicit feedback from workshop participants. The workshop will be 1 ½ to 2 days over the time period of August 28 – 30 in Research Triangle Park, NC. EPA anticipates having approximately 20-25 non-EPA workshop participants, for which a limited number will have travel reimbursed under this work assignment. This work assignment does not include logistical support related to securing a facility or any meeting rooms. EPA has reserved its own meeting room space for these workshops. Support shall consist of the following tasks:

## **B. Specific Requirements (Tasks):**

1. A kick-off meeting shall be held (in person and/or by phone) between the Contractor and WAM to clarify or address questions. The contractor shall maintain communication with the EPA WA Manager (WAM) through weekly phone calls or email updates.
2. A conference room has been reserved on the US EPA campus in RTP for August 28 - 30. EPA shall provide for meeting rooms, and any necessary audiovisual equipment needed for this workshop. EPA will submit to the contractor recommended alternative dates for the workshop in the event the workshop needs to be rescheduled.

Task 1: Pre-meeting support: Administrative and logistical support services for workshop and Data Summit planning may include:

- Providing support to invited participants (non-federal) for travel expense reimbursement.
  - The Contractor shall arrange and provide for transportation, lodging, and logistical support for up to twenty experts asked to participate in the workshop.
- Establishing and monitoring a registration website for each workshop and compile and maintain the workshop registration list. Provide updated registration lists to EPA on a weekly basis after registration opens and more frequently when registration deadlines are approaching.
- Providing participants local information about hotels, restaurants, directions, transportation (airport, airport transportation, etc.), and travel reimbursement issues (per diem, etc.)
- Preparing folders for distribution to attendees at registration including final agenda, meeting roster, survey for participants to fill out, name badges and other meeting materials.
- Managing the collection of any experts' presentations and prepare electronic files needed during the workshop. Load all expert and EPA presentations on the computer to be used during the workshop.
- Working with EPA's onsite facility staff to ensure meeting rooms have AV equipment including microphone, laptop computer, projectors, screen, flip charts, tape, markers etc.
- Setting up webinar, conference call and if applicable video conference capability for remote participation.

## Task 2: Onsite Logistical Support

- Providing staff to support the workshops and the data summit onsite.
- Capturing notes during the discussion including the plenary sessions and breakout groups. The notes should highlight key decisions and action items.
- Managing the registration table to ensure participants sign in, receive the meeting materials and handle any problems workshop participants may encounter.
- Update attendee list at the end of the workshop (remove no-shows, add walk-ins).
- Providing on-site liaison services to work with facility staff to trouble-shoot any problem situations related to AV support or break-out room set-up.
- Collecting the workshop evaluations from participants.

Task 3: Post-meeting support: Administrative and logistical support services for workshop and Data Summit planning may include:

- Process travel expense reimbursements for invited participants (non-federal)
- Summarizing in a report all meeting discussions including key decisions and actions item in a post-meeting summary report. This report should include a listing of all meeting attendees with contact information.

## **IV. SCHEDULE OF DELIVERABLES**

The following table provides a complete list of required work assignment tasks that are to be completed as part of this contract.

<b>Work Assignment Task</b>	<b>Required Completion Date</b>
Initial Contact (listed above) shall be performed.	Within 3 days of award
Establish website for on-line registration	Seven days from award
Submit electronic copies of registration lists and registration materials	Two working days before workshop
Submit updated list of registered attendees, electronic version of presentation materials, and any materials submitted by presenters prior to or following the meeting.	Ten working days following workshop
Post-workshop final report(s)	Ten working days following workshop
Travel Reimbursements	Ten working days following workshop

## **V. V.      Management Controls**

All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

## **VI      Notice Regarding Guidance Provided Under this Project**

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

## **VII. Special Conditions and Assumptions**

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a weekly update to the WAM by telephone or email for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

Travel: Any non-local travel directly chargeable to this work assignment shall be submitted and approved by the Project Officer prior to the travel (see contract clause Local LC-31-08, Approval of Contractor Travel). It is expected that the Contractor will be requested to participate in the workshop in the Research Triangle (NC) area.

EPA GREEN MEETING REQUIREMENTS: When soliciting quotes or offers for meeting and conference services on behalf of the EPA, the Contractor shall follow the contract EPAAR clause 1552.223-71, EPA Green Meetings and conferences. More information about EPA's Green Meetings initiative may be found on the internet at <http://www.epa.gov/oppt/greenmeetings/>.

## **VIII. EPA CONTACT INFORMATION**

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM)  
Melissa McCullough  
919-541-5646



[mccullough.melissa@epa.gov](mailto:mccullough.melissa@epa.gov)

Alternate WAM

Patricia McGhee

919-541-2607

[mcghee.patricia@epa.gov](mailto:mcghee.patricia@epa.gov)

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 2-93				
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:				
Contract Number EP-C-14-001			Contract Period 11/01/2013 To 10/31/2017 Base                      Option Period Number    3			Title of Work Assignment/SF Site Name Workshop				
Contractor ICF INCORPORATED, L.L.C.				Specify Section and paragraph of Contract SOW A. Assessment Issues and Documents						
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input checked="" type="checkbox"/> Work Plan Approval				Period of Performance  From 11/01/2015 To 10/31/2016						
Comments:										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
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Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee: \$0.00				LOE: 0				
11/01/2013 To 10/31/2017										
This Action:		\$47,562.00				372				
Total:		\$47,562.00				372				
Work Plan / Cost Estimate Approvals										
Contractor WP Dated: 07/27/2016		Cost/Fee \$47,562.00				LOE: 372				
Cumulative Approved:		Cost/Fee \$47,562.00				LOE: 372				
Work Assignment Manager Name    Melissa Mccullough  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 919-541-5646 FAX Number:				
Project Officer Name    Melissa Revely-Wilson  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:				
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: FAX Number:				
Contracting Official Name    William Yates  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:				

**EPA**United States Environmental Protection Agency  
Washington, DC 20460**Work Assignment**Work Assignment Number  
2-98☐ Other ☐ Amendment Number:Contract Number  
EP-C-14-001Contract Period 11/01/2013 To 10/31/2016  
Base Option Period Number 2Title of Work Assignment/SF Site Name  
Technical Support for Human HeContractor  
ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

Purpose: ☒ Work Assignment ☐ Work Assignment Close-Out  
☐ Work Assignment Amendment ☐ Incremental Funding  
☐ Work Plan ApprovalPeriod of Performance  
From 11/01/2015 To 10/31/2016

Comments:

☐ Superfund

## Accounting and Appropriations Data

☒ Non-SuperfundSFO  
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## Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2016 Cost/Fee: LOE:

This Action:

Total:

## Work Plan / Cost Estimate Approvals

Contractor WP Dated: Cost/Fee: LOE:

Cumulative Approved: Cost/Fee: LOE:

Work Assignment Manager Name Srinivas Gowda

Branch/Mail Code:

Phone Number: 703-308-6354

FAX Number:

(Signature)

(Date)

Project Officer Name Melissa Revely-Wilson

Branch/Mail Code:

Phone Number: 919-541-0207

FAX Number:

(Signature)

(Date)

Other Agency Official Name Tanisha Brockett

Branch/Mail Code:

Phone Number: 703-305-6937

FAX Number:

(Signature)

(Date)

Contracting Official Name William Yates

Branch/Mail Code:

Phone Number: 513-487-2055

FAX Number:

(Signature)

(Date)

# **PERFORMANCE WORK STATEMENT TECHNICAL SUPPORT FOR HUMAN HEALTH RISK ASSESSMENT**

## **I. INTRODUCTION**

The Office of Research and Development's (ORD) National Center for Environmental Assessment (NCEA) serves as the resource center for the overall process of human health and ecological risk assessment: the integration of hazard, dose-response, and exposure data and models to produce risk characterizations. The organizational structure of the NCEA consists of an immediate office located in Washington, DC and three divisions (Cincinnati, OH; RTP, NC; and Washington, DC). The NCEA occupies a critical position in the ORD between (a) the researchers in other ORD components who are generating new findings and data, and (b) the regulators in the EPA program offices and regions that make regulatory, enforcement, and remedial action decisions.

One of these EPA program offices is the Office of Pesticide Programs (OPP) that is responsible for the regulation of pesticides through the registration and registration review of pesticides as required by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act (FQPA) of 1996.

A central feature of FIFRA is that all pesticides in the United States must be registered with and approved by the EPA, unless specifically exempted (FIFRA section 25), prior to the manufacture, sale and distribution, to ensure that the pesticide poses no serious risks to human health or the environment when used according to the label. OPP is responsible for all registration activities for pesticides, including scientific review and risk-benefit determinations. OPP develops data requirements and guidelines for the conduct of studies by registrants.

The registrants provide data on pesticide product ingredients in support of the establishment of tolerances or exemptions from the requirement of a tolerance for the registration of these products. OPP evaluates the submitted scientific data, and determines whether the data are adequate for making regulatory decisions.

The EPA is also required to conduct a re-evaluation of every pesticide active ingredient every 15 years. This process is known as Registration Review. It can include conducting new risk assessments; determining when additional data are needed to ensure that the pesticide products are up to the current scientific and legal standards required by FIFRA, FQPA, FFDCA, and the Pesticide Registration Improvement Renewal Act (PRIA); reviewing new data on toxicity and human health submitted to support the active ingredient; updating existing registration documents such as Reregistration Eligibility Documents (REDs), Biopesticide Registration Action Documents (BRADs), or Scoping Documents, science memos, Data Evaluation Records

(DERs); and reviewing labels to determine what impact a Registration Review decision makes to the currently approved label.

Data needed to make regulatory decisions for a pesticidal substance begins with the data requirements outlined in 40 CFR Part 158: Data Requirements for Pesticides. This part describes the data and information needed for the various pesticide use patterns: Subpart D<sup>1</sup> for Product Chemistry; Subpart E<sup>1</sup> for product performance, Subpart F<sup>1</sup> for Toxicology; Subpart O<sup>1</sup> for Residue Chemistry; Subpart U for Biochemical Pesticides; Subpart V for Microbial Pesticides; and Subpart W for Antimicrobial Pesticides. Collectively, these data requirements are referred to as “Part 158 data requirements.” The data requirements are further defined in the OCSPP Test Guidelines referenced in the Tasks describe below (<http://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/final-test-guidelines-pesticides-andtoxic>).

## **II. PURPOSE AND SCOPE**

The purpose of this procurement is to provide technical expertise for the review and evaluation of various types of data to assist EPA in meeting its legislative mandates. To support EPA's OPP, the contractor shall, upon request, perform a full review and evaluate various data submitted to support pesticide registration.

The contractor shall supply the necessary resources required for the performance of this contract. The scientific quality of reviews, assessments, reports, model tools, statistical programs and software, and their timely preparation in accordance with negotiated schedules, are of paramount importance in the performance of this contract.

The contractor shall have the necessary technical and scientific expertise, knowledge and experience to successfully perform all of the tasks identified below. In addition, the contractor shall have a quality assurance/quality control program that maintains the quality of products, as well as an ongoing training program. This is intended to ensure that the contract staff produces quality products, and feedback from OPP on needed improvements is communicated to the contractor's staff. The contractor shall maintain and make available upon request complete documentation of QA/QC practices and procedures.

Performance of work under this contract shall be initiated by competitive task orders issued by the Contracting Officer, and will encompass tasks in one or more of the following areas discussed below in Section III (SPECIFIC AREAS OF WORK).

## **III. SPECIFIC AREAS OF WORK**

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<sup>1</sup> And/or Subpart U/V/W in some cases, depending on the type of pesticide

The Contractor shall provide all technical support within the scope of this Performance Work Statement (PWS). The Contractor shall perform tasks, as specified by individual work assignments issued by the Contract Officer (CO), in the following program areas: Statistical Review and Analysis of Human Health Exposure and Toxicity Data

The task(s) which will be issued through work assignments require expertise in statistics, biostatistics, and mathematical modeling.

For many tasks, scientific needs are highly specialized, requiring expert personnel having the knowledge and ability to fully and critically evaluate study methodologies and results in the technical disciplines identified above. Analyses must be scientifically sound and sufficiently documented to withstand intensive critical examination and review by other experts in the relevant disciplines.

### **TASK 1: STATISTICAL ANALYSIS SUPPORT**

The contractor shall provide statistical support for analyses of human health exposure and toxicology studies. The contractor shall review and analyze statistical methods for assessing unit exposures for dermal and inhalation monitoring data for pesticide applicators.

Verification of the statistical analysis is an integral part of the data evaluation process. As such, contractors shall routinely analyze, report, interpret, and summarize statistical results such as basic summary statistics, parametric and non-parametric hypothesis testing (e.g. Dunnett's test, Williams' test, Jonckheere-Terpstra test, etc.), and linear and nonlinear regressions. Types of statistical analyses and reporting also include, but are not limited to, the AEATF's monitoring objective of a relative 3-fold accuracy (i.e., geometric mean, arithmetic mean, and 95th percentile be accurate within 3-fold with 95 percent confidence); reviewing sample size and study design; calculating normalized unit exposures using and comparing empirical estimates, simple random sample estimates, as well as a hierarchical variance component modeling estimates; testing the exposure results for proportionality between exposure and pounds of active ingredient handled; and estimating the threshold of pounds a.i. where exposure is not underestimated.

Evaluations shall state which methods of statistical comparison were used and why the methods were appropriate. They shall also include explanations about the relationship between the doses of the test substance and the presence or absence, incidence, and extent of any type of trend or effect. The contractor shall be able to provide both basic and advanced statistical support for all types of environmental data. Additional examples of statistical support include Bayesian and probabilistic, design of experiments, power analysis, mixed models, time series analysis, multivariate statistics, and categorical data analysis. As requested by the Contractor Officer's Representative (COR), the contractor shall provide feedback and recommendations to the Agency pertaining to the appropriate use and application of various statistical methodologies.

Determine exposure or potential exposure from pollution/contaminant sources (including background levels) by evaluating measured or modeled biological, chemical, or physical concentrations or gradients at the interface between an organism and an environmental medium of concern, as specified in individual work assignments. Estimate internal doses and target organ doses of chemicals.

The contractor shall provide quick turn-around technical support relating to analyses of human health exposure and toxicology studies. Additionally, the contractor shall also assist OPP in interfacing with other Government agency requests, to the extent that such requests are feasible and relate to the general scope of this PWS.

#### **IV. PRODUCT QUALITY**

##### **A. General Risk Assessment Provisions**

In the preparation of any of the scientific documents required by a work assignment, the Contractor may be required to provide the services of experts in the areas of statistics, biostatistics, chemistry, and mathematical modeling. In many of the tasks, the scientific needs are highly specialized; this requires expert personnel with the knowledge and ability to fully and critically evaluate study methodologies and results in the technical disciplines identified above. Unless otherwise specified in a work assignment, products prepared must be state of the art analyses based on expert critical evaluation and analyses of the exposure and toxicity data of the chemical or other stressor. As appropriate, the Contractor shall present qualitative and quantitative biological, toxicological, or biochemical evidence, as well as statistical analysis and a discussion of the strengths and weaknesses of pertinent studies, taking into account current EPA guidance on such matters.

The quality of work products is expected to accurately reflect the state-of-the-art scientific knowledge and current risk assessment methods, including the approaches used by the US EPA. The Contractor may be required to apply newly developed methods in preparation of the documents.

Reports may require detailed or concise summaries of available data in the areas statistics. When appropriate, comprehensive searches of all pertinent literature and data bases shall be performed. The data shall reflect the latest scientific knowledge obtainable. The literature shall be critically evaluated, and accepted EPA risk assessment guidance shall be applied to the data. In the absence of specific EPA guidance, procedures will be developed and applied upon approval by the PO.

##### **B. Quality Assurance/ Quality Control Requirements**

The Contractor is responsible for quality control and quality assurance of all tasks. The Contractor shall ensure that data generated or used for each work assignment is "of the type and quality needed and expected for their intended use" and that all assessment products adhere to a

high standard for quality, including objectivity, utility, and integrity. All documents shall adhere to the OMB data quality guidance for federal information and with the EPA's Information Quality Guidelines.

As specified in each work assignment and prior to starting any work, the Contractor shall prepare either a Quality Assurance Project Plan (QAPP) or a narrative statement that describes the procedures to be used and a list of the data sources and methods. The Contractor must address in the work plan or QAPP how it is going to consider the quality of the secondary data that it uses, and how it is going to consider data uncertainty and variability. Secondary data is defined as the review or use of someone else's environmental or health data that was developed for a different purpose. This includes (but is not limited to) the data used from: citations from the literature searches, hard copies, and computer databases

### **C. Written and Electronic Products**

The Contractor shall provide written and electronic products of high quality, written in a clear, concise style, with a logical organization and presentation of ideas and rationales. The Contractor shall:

1. Use standard formats as specified in "Handbook for Preparing Office of Research and Development Reports," EPA/600/K-95/002, U.S. EPA (1995), or as specified in the work assignment.
2. Perform scientific and technical editing of all products.
3. Provide written products free of grammatical, spelling, and typographical errors, and accurately summarize the information with correct and complete reference citations.
4. Present scientific information in a consistent style that makes it easy for the reader to follow and pay specific attention to it to insure consistent and accurate information content, and appropriate data interpretation throughout the document.

Products not adhering to these standards or guidelines or substantially lacking scientific quality will not be accepted. The Contractor shall use current EPA methods and guidelines for performance of work, unless otherwise specified. The Contractor shall provide printed copies and an electronic copy of all completed work assignment documents prepared in Microsoft Word 2003, or a later version if requested, on compact disks.

## **IV. DELIVERABLES**

- A. Task Reports:** All reports, documents, papers, and data end-points etc., prepared/compiled by the contractor shall be submitted electronically in draft form using agency standard software, science industry standard software, and/or OPP science data repository/workflow portal, or other storage media as specified in the task assignment. The contractor shall



provide the reviews in electronic format (MS Word and/or PDF) delivered by email or other electronic portal or as CD or flash drive, and in hard copy if requested by the WAM, COR or CO.

- B. Other Services:** In performing the services required under this PWS, the contractor shall submit all relevant information used in developing conclusions or options to the COR for all projects for evaluation review and approval. All software and databases developed or enhancements or modifications of existing software or databases performed under this contract; all documentation, notes, preceding versions; all other material pertaining to the development, enhancement, modification and testing of the software and/or databases; and all information and data populating associated databases shall be the property of the agency; will be delivered to the agency upon request or at completion of the task; and cannot be used by the contractor for any other purpose than that specified in a task order without prior written permission by the CO.
- C. Monthly Technical and Financial Management Reports:** The contractor shall submit to the Contract level COR and CO a monthly Technical and Financial Management report in accordance with the requirements stated in the individual task orders.

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 2-98				
						<input checked="" type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001				
Contract Number EP-C-14-001			Contract Period 11/01/2013 To 10/31/2017			Title of Work Assignment/SF Site Name				
			Base                      Option Period Number      2			Tech Support HH Risk Assessmen				
Contractor ICF INCORPORATED, L.L.C.					Specify Section and paragraph of Contract SOW					
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval					Period of Performance  From 11/01/2015 To 10/31/2016					
Comments: This is to correct the total budget as \$15,170. All other terms and conditions remain unchanged.										
<input type="checkbox"/> Superfund    Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> (Max 2)    Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
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Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee: \$0.00				LOE: 0				
11/01/2013 To 10/31/2017										
This Action:		\$15,170.00				95				
Total:		\$15,170.00				95				
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:		08/19/2016		Cost/Fee \$15,170.00		LOE: 95				
Cumulative Approved:				Cost/Fee \$15,170.00		LOE: 95				
Work Assignment Manager Name Srinivas Gowda						Branch/Mail Code:				
_____ (Signature)    (Date)						Phone Number: 703-308-6354				
						FAX Number:				
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<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO <input type="checkbox"/> (Max 2)                      Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee: \$0.00				LOE: 0				
11/01/2013 To 10/31/2017										
This Action:		\$14,844.00				95				
Total:		\$15,495.00				95				
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:		08/19/2016		Cost/Fee \$14,844.00		LOE: 95				
Cumulative Approved:				Cost/Fee \$15,495.00		LOE: 95				
Work Assignment Manager Name Srinivas Gowda						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number: 703-308-6354				
						FAX Number:				
Project Officer Name Melissa Revely-Wilson						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number: 919-541-0207				
						FAX Number:				
Other Agency Official Name						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number:				
						FAX Number:				
Contracting Official Name William Yates						Branch/Mail Code:				
_____ (Signature)                      (Date)						Phone Number: 513-487-2055				
						FAX Number:				

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>						Work Assignment Number 2-99			
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:			
Contract Number EP-C-14-001			Contract Period 11/01/2013 To 10/31/2016 Base                      Option Period Number    2			Title of Work Assignment/SF Site Name Nitrogen Workshop			
Contractor ICF INCORPORATED, L.L.C.				Specify Section and paragraph of Contract SOW Section E, #2					
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance  From 08/08/2016 To 10/31/2016			
Comments:									
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund           <span>Accounting and Appropriations Data</span> <input checked="" type="checkbox"/> Non-Superfund         </div>									
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.									
SFO <input type="checkbox"/> (Max 2)									
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)  (Cents)	Site/Project (Max 8)	Cost Org/Code
1									
2									
3									
4									
5									
Authorized Work Assignment Ceiling									
Contract Period:		Cost/Fee:			LOE:				
11/01/2013 To 10/31/2016									
This Action:									
Total:									
Work Plan / Cost Estimate Approvals									
Contractor WP Dated:				Cost/Fee			LOE:		
Cumulative Approved:				Cost/Fee			LOE:		
Work Assignment Manager Name Patricia Mcghee  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code:		
							Phone Number: 919-541-2607		
							FAX Number:		
Project Officer Name Melissa Revely-Wilson  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code:		
							Phone Number: 919-541-0207		
							FAX Number:		
Other Agency Official Name  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code:		
							Phone Number:		
							FAX Number:		
Contracting Official Name William Yates  <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>							Branch/Mail Code:		
							Phone Number: 513-487-2055		
							FAX Number:		

**WORK ASSIGNMENT**  
**Contract No. EP-C-14-001**  
**WA 2-99**

**Title: Cross-EPA Efforts on Reactive Nitrogen and Co-Pollutants: Science to Inform Action Workshop**

Contract # EP-C-14-001

Current PERIOD OF PERFORMANCE: July 28, 2016 – September 30, 2016

Specify Section & Paragraph that supports use of the contract for this WA: Section E, #2

**I. PURPOSE:**

The purpose of this Work Assignment is to provide administrative and logistical/facilitation support services for a two-day stakeholder workshop. This workshop will be held in the in Research Triangle Park, NC August 31, 2016 starting at 1:00pm through September 2, 2016 ending at 12:00pm at the U.S. Environmental Protection Agency (EPA) facility. This work assignment is consistent with the purpose and scope of Contract EP-C-14-001.

**II. BACKGROUND:**

This workshop will build upon the Science Advisory Board (SAB) recommendations and the Cross-EPA Nitrogen and Co-pollutant Roadmap for greater intra-agency interaction to break down media-based or disciplinary barriers and bring together scientists across the Environmental Protection Agency (EPA) to share their research. EPA scientists in the Safe and Sustainable Water Resources (SSWR), Air, Climate and Energy (ACE), Sustainable and Healthy Communities (SHC), and Human Health Risk Assessment (HHRA) research programs working on nutrient research as well as program office staff in Office of Water (OW) and Office of Air and Radiation (OAR) as well as EPA Regional staff will be invited. Scheduling this workshop early during this time provides EPA scientists in the initial stages of their research the opportunity to learn about related work and identify areas of coordination and collaboration across EPA.

The main goal of the workshop is to provide an opportunity for EPA scientists working on similar issues in different labs and offices to meet and build Office of Research and Development (ORD) and program collaborations. The workshop will enable EPA researchers and program scientists to present the work they are planning/conducting in their tasks (Day 1) and also foster discussion in particular focal areas such as watershed modeling, green infrastructure, water quality trading, human health issues, communication, or ecosystem services.

Day 1 will include a plenary session outlining the Cross-EPA N Roadmap, program office connections, and goals of the workshop, a series of “lightning talks”, followed by a poster or mixer session like the Research Program annual meetings for off-line conversations and connections. We will also create a book of 1-page project abstracts with PI and program scientist contact information that folks can either access on-line or on a small thumb drive.

Day 2 will foster discussion of projects that cut across the focal areas described above. Key scientists from other agencies/universities will evaluate how the EPA N research can collaborate or better link with other N research efforts. Day 2 will end with a discussion of next steps and revisions to the Cross-EPA Nitrogen and Co-pollutant Roadmap to incorporate these new ideas and any other issues relevant to implementation in advance of the BOSC review.

Products: project abstracts book, a workshop summary including presentations, and database of ongoing EPA nutrient-related projects (building on the Roadmap spreadsheets)

The anticipated outcome of the meeting is to advance N<sub>r</sub> research to inform science based management, improve communications, and identify alternative approaches to managing N<sub>r</sub> in an integrated framework.

### **III. STATEMENT OF WORK:**

#### **A. Objective:**

The overall objective of this work assignment (WA) is to provide administrative and logistical support. Support will include the development of a platform for participant registration and access to meeting materials, travel coordination and planning for non-federal meeting participants, onsite meeting support and note taking during the workshop. The workshop date is half a day August 31, all day September 1<sup>st</sup>, and half a day September 2nd. EPA anticipates having approximately 50 workshop participants. This work assignment does not include logistical support related to securing a facility or any meeting rooms. EPA has reserved meeting space on the RTP Campus for this workshop. Administrative and logistical support shall consist of the following tasks:

#### **B. Specific Requirements (Tasks):**

1. The Contractor shall prepare a written work plan describing how the tasks in this SOW will be performed, including a schedule, budget, level of effort, and qualifications of personnel. To facilitate timely preparation of the work plan, a kick-off meeting shall be held (in person and/or by phone) between the Contractor and WAM to clarify or address questions. The contractor shall maintain communication with the EPA WA Manager (WAM) through weekly phone calls or email updates. The EPA Contract Officer shall be notified when expenditures approach 75% of the funded dollar value of the Work Assignment (WA).

2. A kick-off meeting shall be held (in person and/or by phone) between the Contractor and WAM to clarify or address questions. The contractor shall maintain communication with the EPA WA Manager (WAM) through weekly phone calls or email updates.
3. Pre-meeting support: Administrative and logistical support services for workshop planning may include:
  - Maintain a list of invited, confirmed and declined participants.
  - Provide participants local information about hotels, restaurant, directions, transportation (airport, airport transportation, etc).
  - Providing support to invited participants (non-federal) for travel expense reimbursement.
  - The Contractor shall arrange and provide for transportation, lodging, and logistical support for five to not more than six experts asked to participate in the workshop.
  - Develop a method or platform for confirmed participants to register and get materials prior to the meeting.
  - Preparing folders for distribution to attendees at registration including final agenda, meeting roster, survey for participants to fill out, name badges and other meeting materials.
  - Working with EPA's onsite facility staff to ensure meeting rooms have AV equipment including microphone, laptop computer, projectors, screen, flip charts, tape, markers etc.
  - Solicit 1-page abstracts from all invitees using common format, assemble into an abstract book and provide an electronic version of this abstract book to all attendees.
4. Onsite Logistical Support and Reporting
  - Providing staff to support the workshop onsite. Contractor will wear a name badge clearing stating their status as a Contractor.
  - Managing the registration table to ensure participants sign in, receive the meeting materials and handle any problems workshop participants may encounter.
  - Update attendee list at the end of the workshop (remove no-shows, add walk-ins).
  - Providing on-site liaison services to work with facility staff to trouble-shoot any problem situations related to AV support or break-out room set-up.
  - Provide note taking during the workshop

#### **IV. SCHEDULE OF DELIVERABLES**

The following table provides a complete list of required work assignment tasks that are to be completed as part of this contract.

Work Assignment Task	Required Completion Date
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Prepare a written work plan	Within 2 weeks of award
Generate pool of candidates to invite and decide distribution of expertise for travel	Within 2 weeks of award
Solicit abstracts from all attendees	Within one month of award
Prepare registration and material distribution mechanism/platform	August 8-10, 2016.
Update mechanism/platform with materials, including the electronic abstract book	August 17-19, 2016 post meeting
Submit electronic copies of final participant list;	Two working days before the workshop and status updates on registration leading up to events.
Submit meeting summary in electronic form, including final list of attendees, notes, presentations, abstract books and lists of action items and next steps	One month following workshop

## **V. Notice Regarding Guidance Provided Under this Project**

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

## **VI. Special Conditions and Assumptions**

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a weekly update to the WAM by telephone or email for the duration of the work assignment, in addition to the standard reporting requirements of the contract.



Travel: Any non-local travel directly chargeable to this work assignment shall be submitted and approved by the Project Officer prior to the travel (see contract clause Local LC-31-08, Approval of Contractor Travel). It is expected that the Contractor will be requested to participate in a 2-day workshop in the Research Triangle (NC) area on dates to be determined.

EPA GREEN MEETING REQUIREMENTS: When soliciting quotes or offers for meeting and conference services on behalf of the EPA, the Contractor shall follow the contract EPAAR clause 1552.223-71, EPA Green Meetings and conferences. More information about EPA's Green Meetings initiative may be found on the internet at <http://www.epa.gov/p2/green-meetings>.

## **VII. EPA CONTACT INFORMATION**

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Project Officer (PO)  
Melissa Revely-Wilson  
919-541-0207  
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Alternate Work Assignment Manager  
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